

In the Office Action, the Examiner alleges that independent claims 1 and 12 are anticipated by Kowallik and, more particularly, by two specific passages in Kowallik. The first passage is found at column 1, line 33 and lines 33-37 of Kowallik. This passage states that daytime sleepiness is seen in individuals who experience interruptions of their sleep (micro-arousals) which occur in the presence of UAR syndrome because the upper airways are narrowed without being completely obstructed. The second passage is found at column 1, lines 39-42 of Kowallik and is reproduced hereafter:

Large variations in the pressure in the chest are presumably the cause of micro-arousals and may be responsible for subsequent negative effects on the cardiovascular system.

Independent claim 1 is directed to a method of treating functional somatic syndromes comprising the steps of identifying a patient as having a functional somatic syndrome and treating such a patient with an airway stabilization technique. Independent claim 12 is also directed to a method of treating functional somatic syndromes that comprises identifying a patient as having one or more symptom of a functional somatic syndrome and treating such a patient with an airway stabilization technique.

Applicant submits that a *prime facie* anticipation rejection under 35 USC § 102(e) based on the teachings of Kowallik has not been proffered. The foregoing passages do not in any way discuss or mention functional somatic syndromes. In fact, nowhere in the entire disclosure of Kowallik is a functional somatic syndrome even remotely discussed or even suggested. Accordingly, Kowallik cannot anticipate either independent claim 1 or 12 which are directed to a method of treating functional somatic syndromes including a method step of identifying a patient as having a functional somatic syndrome (as in claim 1) or a symptom thereof (as in claim 12). The Kowallik disclosure is limited to addressing sleep apnea and upper airway resistance syndrome (UARS). These forms of sleep disordered

breathing are not functional somatic syndromes. The term "functional somatic syndrome" refers to a specific grouping of medical syndromes that have an unknown cause. It may be that the Examiner is attempting to equate or classify any syndrome involving a body function, such as UARS, as a "functional somatic syndrome" but such an assertion is contrary to Applicant's disclosure. The functional somatic syndromes (FSS), as described previously, are a group of medical syndromes without an apparent cause. The functional somatic syndromes are described and discussed in paragraphs 5-7 of this application. Upon reviewing these paragraphs, it will be clear that Kowallik does not discuss or even allude to any functional somatic syndrome, nor is there anything in Kowallik that teaches or suggests treating a functional somatic syndrome as claimed in independent claims 1 and 12. If the Examiner is attempting to equate or classify any syndrome involving a body function, such as a sleep disordered breathing ailment such as UARS with a functional somatic syndrome, such a conclusion is not supported by Kowallik or Bennett. If such a conclusion is being made or attempted, such a conclusion can only be derived from Applicant's disclosure which is impermissible.

With specific reference to Kowallik, the disclosure of this patent is limited to diagnosing and treating UARS using a source of CPAP that is controlled by a sensor of respiratory rate and EKG. What Applicant has discovered is that functional somatic syndromes are manifestations of sleep disordered breathing and has invented a method of treating functional somatic syndromes using an airway stabilization technique which may be, but is not limited to, a CPAP device or an oral appliance. Neither Kowallik nor Bennett teach or suggest such a discovery or method of treatment. As a result, independent claims 1 and 12 cannot be and are not anticipated by Kowallik, nor does Bennett correct any of the deficiencies discussed hereinabove relating to Kowallik. Accordingly, Applicant requests consideration of the Examiner's rejections of independent claims 1 and 12. It is noted that

Bennett is cited only in connection with claim 10 which depends from independent claim 1. Bennett discloses a method for therapeutic treatment of fibromyalgia which is not pertinent to the subject matter claimed in independent claims 1 and 12.

Claims 4-11 and 15-20 depend directly or indirectly from independent claims 1 and 12, respectively, and distinguish over the cited art for all the reasons discussed hereinabove. Reconsideration of the rejections of claims 4-11 and 15-20 is further respectfully requested. Since Bennett does not correct any of the deficiencies discussed hereinabove in connection with Kowallik, Applicant further requests reconsideration of the rejection of claim 10, which depends from independent claim 1, over the cited combination of Kowallik in view of Bennett. Should the Examiner wish to discuss the claimed subject matter further, he is invited to contact the undersigned at the telephone number provided below. If it would be helpful to expedite prosecution of this application, the inventor, Dr. Avram R. Gold, could be included in such an interview as well.

Respectfully submitted,
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